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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,110	08/26/2003	Yanhong Zhu	13131-0292 (44378/287574)	5892

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,110	ZHU ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *7-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 7-16 are presented for examination.

Applicant's response filed October 20, 2006 to the requirement for restriction dated September 22, 2006 has been received and entered into the present application.

An election of species of delipidated protein particle and, if applicable, additional therapeutic agent that affects lipid metabolism or parameters associated with Alzheimer's disease was inadvertently omitted from the previous restriction requirement.

Accordingly, the requirement for election of species is set forth below and will direct further prosecution of the elected invention.

Requirement for Election of Species

This application contains claims directed to the following patentably distinct species: (1) partially delipidated protein particle and (2) additional therapeutic agent that either affects lipid metabolism or affects parameters associated with Alzheimer's disease.

The species are independent or distinct because:

The species of compounds recited in the present claims (e.g., HDL, LDL, cholesteryl ester transfer protein inhibitors, synthetic HDL compositions, etc.) are structurally, functionally and/or chemically distinct from any one other compound or genus of compounds encompassed by the present claims such that a comprehensive search of the patent and non-patent literature for any one such compound or group of compounds would not necessarily result in a comprehensive search of any one or more of the other compounds or groups recited in the claims. Additionally, in consideration of the number and significant chemical and structural variability of compounds actually claimed by such a genus, the disparate nature and breadth of compounds encompassed by this genus precludes a quality examination on the merits, not only because a burdensome search would be required for the entire scope of the claim(s), but also because the consideration of the findings of such a search for compliance with the

statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112, would be unduly onerous. Furthermore, though Applicant has recognized a common functionality to the claimed compounds, e.g., that they are effective to treat Alzheimer's disease and/or affect lipid metabolism, it remains that the art does not necessarily recognized such a function as being shared by the entire claimed genus of compounds and, as a result, does not necessarily recognize their equivalency or interchangeability. Additionally, it also remains that the art may recognize an advantageous use for the compound in achieving the presently claimed objective that is not necessarily tied to its function in lipid metabolism or affecting parameters associated with Alzheimer's disease.

Election of species should be made consistent with the following instructions:

Applicant is required to elect a **single administration scenario** selected from any one of the following options:

(i) administration of a partially delipidated lipoprotein particle alone; **or**

(ii) administration of a partially delipidated lipoprotein particle in combination with a therapeutic agent that affects lipid metabolism or a therapeutic agent that affects parameters associated with Alzheimer's disease.

Election of administration scenario (i) requires the election of a **single disclosed specie** of partially delipidated lipoprotein particle from those specifically claimed (see, e.g., claims 9-10) **or** a generic partially delipidated lipoprotein particle not listed in claims 9-10.

Election of administration scenario (ii) requires the following elections:

(A) Election of a **single disclosed specie** of partially delipidated lipoprotein particle from those specifically claimed (see, e.g., claims 9-10) **or** a generic partially delipidated lipoprotein particle not listed in claims 9-10; **and**

(B) Election of a **single disclosed specie** of therapeutic agent that either affects lipid metabolism or parameters associated with Alzheimer's disease from those specifically disclosed (see, e.g., page 18,

line 6-page 22, line 31) **or** a generic therapeutic agent that either affects lipid metabolism or parameters associated with Alzheimer's disease not specifically disclosed. Applicant must identify both the **single disclosed specie** that is elected **and** the functional genus to which it belongs (e.g., cholesteryl ester transfer protein inhibitor, synthetic HDL compounds, etc.).

Applicant is cautioned that the election of a particular specie or combination of species, wherein the elected specie or combination of species is not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

Currently, claims 7-16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the elected specie(s) that are elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

January 5, 2007

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER